AMENDED IN SENATE APRIL 14, 2004 AMENDED IN SENATE APRIL 1, 2004

SENATE BILL

No. 1307

Introduced by Senator Figueroa

February 17, 2004

An act to amend Sections 4043, 4053, 4054, 4059.5, 4081, 4100, 4105, 4110, 4160, 4164, 4165, 4166, 4196, 4301, 4305.5, 4331, and 4400 of, to amend, repeal, and add Section 4163 of, to add Sections 4021.5, 4034, 4022.5, 4034, 4053.1, 4126.5, 4163.5, and 4168 to, to add and repeal Section 4169 of, and to repeal and add Sections 4161 and 4162 of, the Business and Professions Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, as amended, Figueroa. Wholesalers and manufacturers of dangerous drugs and devices.

(1) Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and wholesalers of dangerous drugs or dangerous devices by the Pharmacy Board. Existing law requires that dangerous drugs or dangerous devices be dispensed only by licensed pharmacists and only to certain persons or entities. Existing law provides certain exemptions from this requirement for manufacturers, veterinary food-animal drug retailers, and wholesalers, including those that employ sufficient qualified supervision by a person who possesses a certificate of exemption. Existing law also requires the board to take action against a licensee who is guilty of unprofessional conduct, as defined. Existing law makes a violation of the Pharmacy Law a crime.

This bill, would revise the list of persons to whom a pharmacy may furnish dangerous drugs. The bill would also revise the exemption

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provisions related to manufacturers, veterinary food-animal drug retailers, and wholesalers, and would change the certificate of exemption requirement to a requirement of licensure as a designated representative, as defined. The bill would require a wholesaler to keep track of and report to the board excessive purchases of dangerous drugs by a closed door pharmacy, as defined, and would make the clearly excessive furnishing of dangerous drugs to a closed door pharmacy by a wholesaler unprofessional conduct. The bill would make other related changes.

This bill would, on and after January 1, 2007, would require a pedigree, as defined, to accompany each distribution of a dangerous drug, except that the California State Board of Pharmacy is authorized to—the extend the compliance date to January 1, 2008, under specified circumstances. It would, on and after that date, prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug or device without a pedigree, and would prohibit a wholesaler or pharmacy from acquiring a dangerous drug or device without receiving a pedigree.

(2) Existing law prohibits a person from acting as a wholesaler of dangerous drugs or devices without a license.

This bill would require dangerous drugs or dangerous devices to be acquired from a person authorized by law to possess or furnish them. The bill would exempt a licensed drug manufacturer that only ships drugs of its own manufacture from the provisions governing wholesalers, except for the prohibition against furnishing dangerous drugs or devices to an unauthorized person.

(3) Existing law imposes certain licensing and registration requirements on out-of-state manufacturers and wholesalers doing business in this state, and on their principals.

This bill would delete these requirements. The bill instead would make a person located outside the state that ships, mails, or delivers dangerous drugs or dangerous devices into this state a nonresident wholesaler. The bill would require a nonresident wholesaler to meet specified licensing and reporting requirements, to comply with directions and requests for information, to maintain records in readily retrievable form of dangerous drugs or dangerous devices sold, traded, or transferred to persons in this state, and to designate an exemptee-in-charge to be responsible for compliance with laws governing wholesalers.

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(4) Existing law requires any manufacturer who sells or transfers a dangerous drug or dangerous device into this state or who receives a dangerous drug or dangerous device from a person in this state to, upon request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer. Existing law makes a manufacturer who fails or refuses to comply with that request subject to a citation and a fine, an order of abatement, or both.

This bill instead would apply these provisions to a wholesaler licensed by the board. The bill would delete the provision that makes the failure or refusal to comply with a request subject to a citation and a fine, an order of abatement, or both. The bill would require a wholesaler to submit a surety bond of \$100,000, or an equivalent means of security, for each site to be licensed.

(5) The bill would prohibit a county or municipality from issuing a business license for an establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board.

The bill would prohibit a person or entity from purchasing, trading, selling, or transferring a dangerous drug or device under specified circumstances, including if he or she knew, or reasonably should have known, the drug or device was adulterated or misbranded. The bill would make a violation of those provisions subject to a specified fine.

The bill would specify to whom a pharmacist may furnish dangerous drugs.

- (6) Because a violation of the requirements and prohibitions created by this bill would be a crime, the bill would impose a state-mandated local program.
- (7) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- SECTION 1. Section 4021.5 is added to the Business and
- 2 Professions Code, to read:

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4021.5. (a) "Closed door pharmacy" means a pharmacy that purchases dangerous drugs or dangerous devices for a limited patient population in limited care settings and that is not open for dispensing dangerous drugs and dangerous devices to the general population.

- (b) It is the intent of the Legislature to enact reasonable "due diligence" requirements for wholesalers supplying a closed
- (b) A closed door pharmacy shall be separately designated on the pharmacy license issued by the board.
- SEC. 2. Section 4022.5 is added to the Business and Professions Code, to read:
- 4022.5. (a) "Designated representative" means individual to whom a license has been granted pursuant to Section 4053.
- representative-in-charge" (b) "Designated designated representative or a pharmacist who is the supervisor or manager of a wholesaler or veterinary food-animal drug retailer.
- SEC. 3. Section 4034 is added to the Business and Professions Code, to read:
- 4034. (a) "Pedigree" means a record, in written or electronic form, containing information regarding each transaction involving a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug.
 - (b) A pedigree shall include all of the following information:
- (1) The source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source.
- (2) The quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.
- (3) The business name, address, and if appropriate, the state 36 license number, including a California license number if available, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

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- (4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.
 - (c) This section shall become operative on January 1, 2007. SEC. 3.
- SEC. 4. Section 4043 of the Business and Professions Code is amended to read:
- 4043. "Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, or agent, including a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

SEC. 4.

- SEC. 5. Section 4053 of the Business and Professions Code is amended to read:
- 4053. (a) Subdivision (a) of Section 4051 shall not apply to a manufacturer, veterinary food-animal drug retailer, or wholesaler if the board shall find that sufficient, qualified supervision is employed by the manufacturer, veterinary food-animal drug retailer, or wholesaler that employs a designated representative to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).
- (b) An individual employed by a manufacturer, veterinary food-animal drug retailer, or wholesaler may apply for an exemption from Section 4051 a designated representative license. In order to obtain and maintain that exemption license, the individual shall meet *all* of the following requirements:
- (1) He or she shall be a high school graduate or possess a general education development equivalent.
- (2) He or she shall have a minimum of one year of paid work experience, *in the past three years*, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

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(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

- (A) Knowledge and understanding of state California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
- (B) Knowledge and understanding of state California law and federal law relating to the distribution of controlled substances.
 - (C) Knowledge and understanding of quality control systems.
- (D) Knowledge and understanding of the United States 10 Pharmacopoeia standards relating to the safe storage and handling of drugs.
 - (E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.
 - (4) The board may, by regulation, require training programs to include additional material.
 - (5) The board may, by regulation, require training programs to include additional material.
 - (6) The board shall may not issue a certificate of exemption license as a designated representative until the applicant provides proof of completion of the required training to the board.
 - (c) The manufacturer, veterinary food-animal drug retailer, or wholesaler shall not operate without a pharmacist or an individual in possession of a certificate of exemption a designated representative on its premises.
 - (d) Only a pharmacist or an individual in possession of a certificate of exemption a designated representative shall prepare and affix the label to veterinary food-animal drugs.
 - SEC. 6. Section 4053.1 is added to the Business and Professions Code, to read:
 - 4053.1. (a) Certificates of exemption issued or renewed pursuant to Section 4053 prior to January 1, 2005, shall remain valid until their expiration date or until January 1, 2006, whichever date is earlier.
 - (b) Individuals in possession of a current and valid certificate of exemption shall be issued a license as a designated representative if the individual satisfies the requirements of Section 4053 and pays the fee required by subdivision (i) of Section 4400.
- 39 (c) This section shall become inoperative and be repealed on January 1, 2006, unless a later enacted statute, that becomes

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1 operative on or before December 31, 2005, amends or repeals that 2 date.

- SEC. 7. Section 4054 of the Business and Professions Code is amended to read:
- 4054. Section 4051 shall not apply to a manufacturer, or wholesaler, or other supplier of dialysis drugs and devices distributed that provides dialysis drugs and devices directly to patients if the board finds that sufficient, qualified supervision is employed by the manufacturer, wholesaler, or supplier adequately to safeguard and protect the public health.
- SEC. 8. Section 4059.5 of the Business and Professions Code is amended to read:
- 4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and must-shall be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge. Where a licensee is permitted to operate through an exemptee a designated representative, the exemptee designated representative may sign for and receive the delivery.
- (b) A dangerous drug or dangerous device transferred, sold, or delivered to any person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.
- (c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices.
- (d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. Any—A person or entity receiving delivery of any dangerous drugs or devices, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drugs or dangerous devices.

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(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to any person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the drugs or devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the drugs or devices are to be delivered shall include, but not be limited to, determining that the recipient of the drugs or devices is authorized by law to receive the drugs or devices.

- SEC. 9. Section 4081 of the Business and Professions Code is amended to read:
- 4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
- (b) The owner, officer, and partner of any—a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee designated representative-in-charge, for maintaining the records and inventory described in this section.
- (c) The pharmacist-in-charge or exemptee designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or exemptee designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.
 - (d) This section shall become operative on July 1, 2001.
- 39 SEC. 10. Section 4100 of the Business and Professions Code 40 is amended to read:

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4100. Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, every—a pharmacist, intern pharmacist, technician, or exemptee designated representative shall notify the executive officer of the board of the change of address or change of name.

- SEC. 11. Section 4105 of the Business and Professions Code is amended to read:
- 4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.
- (b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.
- (c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.
- (d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the exemptee designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.
- (e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.
- (2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.
 - (f) This section shall become operative on July 1, 2001.
- SEC. 12. Section 4110 of the Business and Professions Code is amended to read:
- 39 4110. (a) No person shall conduct a pharmacy in the State of 40 California unless he or she has obtained a license from the board.

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A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

- (b) The board may, at its discretion, issue a temporary permit license, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit license fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit license to conduct a pharmacy. When needed to protect public safety, a temporary permit license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit license was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder licensee or service by certified mail, return receipt requested, at the permitholder's licensee's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder licensee be deemed to have a vested property right or interest in the permit license.
- (c) An applicant for either the issuance or renewal of a pharmacy license that meets the definition of a closed door pharmacy in Section 4021.5 shall notify the board on a form approved by the board.
- SEC. 13. Section 4126.5 is added to the Business and Professions Code, to read:
- 4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:
- 36 (1) The wholesaler or manufacturer from whom the dangerous drug was purchased *acquired*.
 - (2) A licensed reverse distributor.
- 39 (3) Another pharmacy or wholesaler to alleviate temporary 40 shortages a temporary shortage of a dangerous drug that could

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result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

- (4) A patient pursuant to a prescription or as otherwise authorized by law.
- (5) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
- (b) Notwithstanding any other provision of law, a violation of this section by either a closed pharmacy or a person engaged in a prohibited transaction with a closed pharmacy may subject the persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.
- (c) For notifications made on and after January 1, 2005, the Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

SEC. 5.

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- SEC. 14. Section 4160 of the Business and Professions Code is amended to read:
- 4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
- (b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
- (c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.
- (d) The board shall not issue or renew a wholesaler license until 36 the wholesaler designates an exemptee-in-charge identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge designated representative. The designated representative-in-charge shall be responsible for the wholesaler's

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compliance with state and federal laws governing wholesalers. A wholesaler shall designate identify, and notify the board of, a new exemptee-in-charge designated representative-in-charge within 30 days of the date that the prior exemptee-in-charge designated 5 representative-in-charge ceases to be exemptee-in-charge designated representative-in-charge. A pharmacist may be designated identified as the exemptee-in-charge designated 8 representative-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means 10 a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

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- (e) A drug manufacturer licensed pursuant to Section 111615 of the Health and Safety Code that only ships dangerous drugs of its own manufacture is exempt from this section.
- (f) The board may issue a temporary license, upon conditions 18 and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a wholesaler.

22 SEC. 6.

Section 4161 of the Business and Professions Code SEC. 15. 24 is repealed.

SEC. 7.

- 26 SEC. 16. Section 4161 is added to the Business and 27 Professions Code, to read:
 - 4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.
- (b) A nonresident wholesaler shall be licensed by the board 32 prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.
- 34 (c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler. Each 35 from or through which dangerous drugs or dangerous devices are 36 shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.

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(d) An applicant for a nonresident wholesaler license shall disclose to the board the names, locations, and titles of each of the following:

- (d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in the following information:
 - (1) Its agent for service of process in this state.

- 9 (2) Its principal corporate officers, as specified by the board, if 10 any.
 - (3) Its general partners, as specified by the board, if any.
 - (4) Its owners, if the applicant is not a corporation or partnership.
 - (e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
 - (f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board .
 - (g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
 - (h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
 - (i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler designates an exemptee-in-charge identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the exemptee-in-charge designated representative-in-charge.
 - (j) The exemptee-in-charge designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall designate identify and

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notify the board of a new exemptee-in-charge designated representative-in-charge within 30 days of the date that the prior exemptee-in-charge designated representative-in-charge ceases 3 4 theexemptee-in-charge designated to be 5 representative-in-charge.

- (k) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053 or a registered pharmacist who is the supervisor or manager of the facility.
- (k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.
- (1) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

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SEC. 17. Section 4162 of the Business and Professions Code is repealed.

SEC. 9.

- SEC. 18. Section 4162 is added to the Business and Professions Code, to read:
- 4162. (a) A wholesaler that applies to the board for a wholesaler license or the renewal of a wholesaler license shall
- 4162. (a) An applicant for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000) for each site to be licensed, or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or 30 financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.
 - (b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of after the order imposing the fine, or costs become final. The board may make a claim against the bond or security until one year after the license ceases to be valid, or until 60 days after the conclusion of any authorized administrative or legal proceeding, including an appeal, that involves the licensee, whichever occurs later..

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SEC. 10.

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2 SEC. 19. Section 4163 of the Business and Professions Code 3 is amended to read:

- 4163. (a) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.
- (b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.
- (b) No person shall acquire dangerous drugs or dangerous devices from a person not authorized by law to possess or furnish those dangerous drugs or dangerous devices.
- (c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date. SEC. 11.
- SEC. 20. Section 4163 is added to the Business and Professions Code, to read:
- 4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.
- (b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.
- (c) A wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug or dangerous device without providing a pedigree.
- (d) A wholesaler or pharmacy may not acquire a dangerous drug or dangerous device without providing a pedigree.
 - (e) This section shall become operative on January 1, 2007. SEC. 12.
- 30 SEC. 21. Section 4163.5 is added to the Business and 31 Professions Code, to read:
 - 4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Section 4163 until
- 34 January 1, 2008, if it determines that manufacturers, wholesalers,
- 35 or pharmacies require additional time to implement electronic
- 36 technologies to track the distribution of dangerous drugs within
- 37 the state. A determination by the board to extend the deadline for
- 38 providing pedigrees shall not be subject to the requirements of
- 39 Chapter 3.5 (commencing with Section 11340) of Part 1 of
- 40 Division 3 of Title 2 of the Government Code.

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SEC. 13.

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Section 4164 of the Business and Professions Code 2 SEC. 22. 3 is amended to read:

- 4164. (a) A wholesaler licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.
- (b) A wholesaler shall report excessive purchases of dangerous 10 drugs by closed door pharmacies to the board.
- (c) A wholesaler shall develop and maintain a system for tracking individual sales of dangerous drugs to closed door pharmacies. The system shall be capable of identifying purchases 14 by an established customer that vary significantly from prior ordering patterns for that customer.
 - (d) Upon written, oral, or electronic request by the board, a wholesaler shall furnish that data, or any specific portion thereof, to the board in written, hardcopy, or electronic form.

SEC. 14.

- SEC. 23. Section 4165 of the Business and Professions Code 21 is amended to read:
- 4165. A wholesaler licensed by the board who sells or 23 transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.

SEC. 15.

- SEC. 24. Section 4166 of the Business and Professions Code 30 is amended to read:
- 4166. (a) Any wholesaler that uses the services of any carrier, 32 including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.
 - (b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

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SEC. 25. Section 4168 is added to the Business and Professions Code, to read:

- 4168. A county or municipality may not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board. For purposes of this section, an "establishment" is the licensee's physical location in California. SEC. 17.
- SEC. 26. Section 4169 is added to the Business and Professions Code, to read:
 - 4169. (a) A person or entity may not do any of the following:
- (1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy, in violation of Section 4163.
- (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
- (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as set forth in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
- (4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.
- (5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.
- (b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.
- (c) The Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax funds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes established by the Franchise Tax Board for this purpose. That amount shall be

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1 forwarded to the board for deposit in the Pharmacy Board 2 Contingent Fund.

- (d) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date. SEC. 18.
- SEC. 27. Section 4169 is added to the Business and Professions Code, to read:
 - 4169. (a) A person or entity may not do any of the following:
 - (1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.
 - (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
 - (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as set forth in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
 - (4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.
 - (5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.
 - (b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.
 - (c) The Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax funds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.
- (d) This section shall become operative on January 1, 2007.SEC. 19.

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SEC. 28. Section 4196 of the Business and Professions Code is amended to read:

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- 4196. (a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.
- (b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.
- (c) No person other than a pharmacist, an intern pharmacist, an exempt person a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or exemptee designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.
- (d) The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer designates an exemptee-in-charge identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that exemptee designated representative. The exemptee-in-charge designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. Each veterinary food-animal drug retailer shall-designate identify, and notify the board of. new exemptee-in-charge designated representative-in-charge within 30 days of the date that the prior exemptee-in-charge designated representative-in-charge ceases

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1 to be exemptee-in-charge designated representative-in-charge. A
2 pharmacist may be <u>designated</u> identified as the
3 exemptee-in-charge designated representative-in-charge.

- (e) For purposes of this section, "exemptee in charge" designated representative-in-charge means a person granted a certificate of exemption designated representative license pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.
- 9 SEC. 29. Section 4301 of the Business and Professions Code 10 is amended to read:
 - 4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
 - (a) Gross immorality.
 - (b) Incompetence.
 - (c) Gross negligence.
 - (d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.
 - (e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.
 - (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
 - (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
 - (h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person

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or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

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- (i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering or offering to sell, furnish, give away, or administer any controlled substance to an addict.
- (j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.
- (k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.
- (1) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.
- (m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States

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Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program.

The record of the compromise is conclusive evidence of

5 unprofessional conduct. 6

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- (n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.
- (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.
- (p) Actions or conduct that would have warranted denial of a license.
- (q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.
- (r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.
- (s) The clearly excessive furnishing of dangerous drugs to a closed door pharmacy by a wholesaler. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but shall not be limited to, the amount of dangerous drugs furnished to a closed door pharmacy, the previous ordering pattern of the closed door pharmacy, and where and to whom the closed door pharmacy distributes the dangerous drugs.
- SEC. 30. Section 4305.5 of the Business and Professions Code is amended to read:
- 34 4305.5. (a) Any A person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, shall 35 notify the board within 30 days of the termination of employment 36 of any pharmacist or exemptee who takes charge of, or acts as 37 manager of the licensee the designated representative-in-charge. 38
- Failure to notify the board within the 30-day period shall constitute 39
- 40 grounds for disciplinary action.

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(b) Any A person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of any pharmacist or exemptee who takes charge of, or acts as manager of the licensee the designated representative-in-charge, and who continues to operate the licensee in the absence of a pharmacist or an exemptee approved the designated representative-in-charge for that location, shall be subject to summary suspension or revocation of his or her license to conduct a wholesaler or veterinary food-animal drug retailer.

- (c) Any pharmacist or exemptee who takes charge of, or acts as manager A designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.
- SEC. 31. Section 4331 of the Business and Professions Code is amended to read:
- 4331. (a) Any A person who is neither a pharmacist nor an exemptee a designated representative and who takes charge of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices except as otherwise provided in this chapter is guilty of a misdemeanor.
- (b) Any A person who has obtained a license to conduct a veterinary food-animal drug retailer and who fails to place in charge of that veterinary food-animal drug retailer a pharmacist or exemptee designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or exemptee designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.
- (c) Any A person who has obtained a license to conduct a wholesaler and who fails to place in charge of that wholesaler a pharmacist or exemptee designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or exemptee designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

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1 SEC. 32. Section 4400 of the Business and Professions Code 2 is amended to read:

- 4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:
- (a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400).
- (b) The fee for a nongovernmental pharmacy annual renewal shall be one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250).
- (c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars (\$155) and may be increased to one hundred eighty-five dollars (\$185).
- (d) The fee for regrading an examination shall be seventy-five dollars (\$75) and may be increased to eighty-five dollars (\$85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.
- (e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars (\$115) and may be increased to one hundred fifty dollars (\$150).
- (f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).
- (g) The fee for a hypodermic license and renewal shall be ninety dollars (\$90) and may be increased to one hundred twenty-five dollars (\$125).
- (h) The fee for application and investigation for an exemptee license under a designated representative license issued pursuant to Section 4053 shall be seventy-five dollars (\$75) and may be increased to one hundred dollars (\$100), except for a veterinary food-animal drug retailer exemptee designated representative, for whom the fee shall be one hundred dollars (\$100).
- (i) The fee for an exemptee a designated representative license and annual renewal under Section 4053 shall be one hundred ten dollars (\$110) and may be increased to one hundred fifty dollars (\$150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee designated representative license shall be one hundred fifty dollars (\$150), for renewal one hundred ten dollars (\$110), which may be increased to one

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hundred fifty dollars (\$150), and for filing a late renewal fifty-five dollars (\$55).

- (j) The fee for a nonresident wholesaler's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).
- (k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).
- (*l*) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.
- (m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars (\$165) and may be increased to one hundred seventy-five dollars (\$175).
- (n) The fee for an intern license or extension shall be sixty-five dollars (\$65) and may be increased to seventy-five dollars (\$75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars (\$20).
- (o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.
- (p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars (\$30).
- (q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars (\$60) and may be increased to one hundred dollars (\$100).
- (r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.
- (s) The fee for any applicant for a clinic permit is three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400) for each permit. The annual fee for renewal of the permit

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is one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250) for each permit.

- (t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50). The biennial renewal fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50).
- (u) The fee for a veterinary food-animal drug retailer license 10 shall be four hundred dollars (\$400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars (\$250).
 - (v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars (\$30).

SEC. 20.

California Constitution.

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SEC. 33. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the